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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,151	04/07/2004	Preston Keusch	020366	8963

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EXAMINER	
GRAY, PHILLIP A	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,151	KEUSCH ET AL.	
	Examiner	Art Unit	
	Phillip Gray	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) *32,33,63 and 64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-31,34-62 and 65-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to applicant's communication filed on 5/25/2006. Elected claims 1-31,34-62, and 65-78 are pending and rejected below. Claims 32-33 and 63-64 are withdrawn, see discussion below.

Election/Restrictions

Claims 32-33 and 63-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/25/2006.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claim 2 is objected to because of the following informalities: It is unclear of what "levels" are degraded to no more then 90%. Is it volume, weight, or some other property? Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-28, 34-35, 37-39, 42-43, 46-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Jain et al. (U.S. Patent Number 6,629,968). Jain et al. discloses a "self storage stable iontophoresis reservoir-electrode and iontophoretic system incorporating the reservoir-electrode". Jain discloses a sealed electrode assembly to delivery drugs with an anode (see figures 1-11), first silver/silver chloride electrode

(104), donor hydrogel comprising epinephrine (figure 2), a local lidocaine anesthetic, a second silver/silver chloride electrode and return hydrogel (near 108), a backing (110), dielectric traces (figure 2), printed silver/silver chloride-containing ink (115), hydrogel comprising polyvinylpyrrolidone and sodium metabisulfite (see paragraphs at column 9).

The Electrode/Anode assembly is fully capable of being physically, chemically, electronically, electrochemically, or microbiologically stable for at least 10, 12, 18, 24, 36 or 48 months at 25 degrees Celsius, or 6 months at 40% Celsius, or 12 months at 30 degrees Celsius. Further the Epinephrine is fully capable of the abilities of "degrades no more than 90% of the original level for at least 24 months at 25 degrees C" and "degrades to no more than about 95% wt. of original levels in 24 months at 25 degree Celsius, or 94% wt. of original levels in 18 months at 25 degree Celsius. These limitations are implicitly capable in the prior art of record. Further the claim limitations regarding stability and degradation are only functional and there is no evidence to any teaching away. The prior art of record explicitly discloses all physical, chemical and structural elements and is fully capable of the stability and degradation requirements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 18, 20-22, 26, 29-31, 36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jain et al. (U.S. Patent Number 6,629,968). Jain discloses a device that satisfies all structural, chemical, and physical limitations of the claims, and it is inherent in the prior art that the functional limitations are disclosed and in the alternative are obvious over Jain.

Concerning claim 18, Jain et al. discloses the claimed invention except for "the hydrogel is about 17% wt. polyvinyl pyrrolidone". It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the polyvinyl pyrrolidone of Jain at a wt of about 17%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233 (CCPA 1955).*

Concerning claim 20-22, 36, Jain et al. discloses the claimed invention except for the sodium metabisulfite amount equal, less then 110%, or about 101%, "...of sodium

metabisulfite equal to a minimal amount needed to scavenge oxygen for at least 24 months". It would have been obvious to one having ordinary skill in the art at the time the invention was made adjust the sodium metabisulfite amount equal, less then 110%, or about 101%, "...of sodium metabisulfite equal to a minimal amount needed to scavenge oxygen for at least 24 months", since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

Concerning claim 26, Jain et al. discloses the claimed invention except for the donor hydrogel comprises lidocaine HCL and epinephrine bitartrate in about a 70-125:1 mass ratio. If not inherent from Jain et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to formulate a hydrogel comprising lidocaine HCL and epinephrine bitartrate in about a 70-125:1 mass ratio, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233 (CCPA 1955).*

Claims 29-31, 40-41, 59-62, and 65-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. in view of Keusch et al. (U.S. Patent Application Number 2003/0055405 A1). Jain discloses the claimed invention except for packaging the drug delivery device under an inert gas of nitrogen. Keusch teaches that it is known to package the drug delivery device under an inert gas of nitrogen as set forth in paragraph [0063] to provide a non-reactive and sterile environment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

modify the drug delivery device as taught by Jain with packaging the drug delivery device under an inert gas of nitrogen as taught by Keusch, since such a modification would provide the drug delivery device with the procedure of packaging the drug delivery device under an inert gas of nitrogen for providing non-reactive and sterile environment.

Concerning claims 40-41, Jain et al. in view of Keusch et al. discloses the claimed invention except for an anesthetic of one of bupivacaine, etidocaine, mepivacaine, ropivicaine and prilocaine. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have and anesthetic other then lidocaine of one of bupivacaine, etidocaine, mepivacaine, ropivicaine and prilocaine, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).*

Concerning claims 44-45, 50-55, 66-68, 73-78, if not implicit in the prior art of record, in the alternative it would have been obvious to modify the percentage weights of the lidocaine, epinephrine, sodium metabisulfite, or sodium chloride. Jain et al. in view of Keusch et al. discloses the claimed invention except if not implicit, in the alternative for modifying the percentage weights of the lidocaine, epinephrine, sodium metabisulfite, or sodium chloride as disclosed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the percentage weights of the lidocaine, epinephrine, sodium metabisulfite, or sodium chloride as disclosed, since it has been held to be within the general skill of a worker in

the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PAG

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER